II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1280

of 2 August 2021

as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ([1]), and in particular Article 95(8) thereof,

Whereas:

(1) Article 93(1)(j) of Regulation (EU) 2019/6 requires the holders of a manufacturing authorisation to use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practice for active substances.

(2) Article 95(1) of Regulation (EU) 2019/6 requires importers, manufacturers and distributors of active substances used as starting materials in veterinary medicinal products, that are established in the Union, to comply with good manufacturing practice or good distribution practice, as applicable.

(3) Measures on good distribution practice should ensure the identity, integrity, traceability and quality of active substances used as starting materials in veterinary medicinal products during their movements from the premises where they are manufactured to the manufacturers of veterinary medicinal products by means of various modes of transport and by the use of various storage methods, as well as that those active substances remain within the legal supply chain during storage and transport.

(4) Several international standards and guidelines on good distribution practice exist for active substances for medicinal products for human use ([2]), ([3]). At Union level, guidelines on good distribution practice have been adopted only in respect of active substances for medicinal products for human use ([4]). Corresponding measures in the veterinary

([1]) OJ L 4, 7.1.2019, p. 43.

([2]) Good trade and distribution practices for pharmaceutical starting materials. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016: Annex 6 (WHO Technical Report Series, No 996).

([3]) Guidelines on the principles of Good Distribution Practice of active substances for medicinal products for human use, PIC/S, PI 047-1 Annex, 1.7.2018.

([4]) Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01) (OJ C 95, 21.3.2015, p. 1).

domain should take into account the experience gained with the application of the current system under Directive 2001/83/EC of the European Parliament and of the Council ([5]) in light of the similarities and potential differences between the requirements on good distribution practice for active substances used as starting materials in medicinal products for human use and in veterinary medicinal products.

(5) A significant number of active substances are used as starting materials both in medicinal products for human use and in veterinary medicinal products. Importers, manufacturers and distributors often deal with such active substances. In addition, good distribution practice inspections for both types of medicinal products are often to be performed by the same competent authority experts. Therefore, in order to avoid unnecessary administrative burden on the industry and the competent authorities, it is practical to apply similar measures to the veterinary domain as in the human domain, unless specific needs dictate otherwise.

(6) In order not to affect negatively the availability of veterinary medicinal products in the Union, the good distribution practice requirements for active substances used as starting materials in veterinary medicinal products should not be more stringent than the corresponding ones for those used as starting materials in medicinal products for human use.

(7) The measures on good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation should ensure consistency with and complement the implementing measures on good manufacturing practice for veterinary medicinal products and active substances used as starting materials provided for in Article 93(2) of Regulation (EU) 2019/6 and good distribution practice for veterinary medicinal products provided for in Article 99(6) of that Regulation.

(8) Relevant sections of good distribution practice for active substances used as starting materials in veterinary medicinal products should also be adhered to by third-party actors involved in the distribution of active substances used as starting materials in veterinary medicinal products and should be part of their contractual obligations. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified active substances used as starting materials in veterinary medicinal products.

(9) A quality system is required to ensure that the objectives of good distribution practice are achieved and should clearly set out responsibilities, processes and risk management principles in relation to the activities of the persons involved throughout the distribution chain. That quality system should be the responsibility of the organisation's management, requires their leadership and active participation, and should be supported by personnel commitment.

(10) The correct distribution of active substances used as starting materials in veterinary medicinal products relies significantly on an adequate number of competent personnel to carry out all the tasks for which the importers, manufacturers and distributors of active substances used as starting materials in veterinary medicinal products are responsible. Individual responsibilities should be clearly understood by personnel and be recorded.

(11) The persons distributing active substances used as starting materials in veterinary medicinal products should have suitable and adequate premises, installations and equipment, in order to ensure proper storage and distribution of active substances used as starting materials in veterinary medicinal products.

(12) Good documentation should be an essential part of any quality system. Written documentation should be required in order to prevent errors from oral communication and permit the tracking of relevant operations during the distribution of active substances used as starting materials in veterinary medicinal products. All types of documents should be defined and adhered to.

(13) Procedures should describe all distribution activities that affect the identity, traceability and quality of the active substances used as starting materials in veterinary medicinal products.

([5]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(14) Records of all significant activities or events should be made and kept to ensure the traceability of the origin and destination of active substances used as starting materials in veterinary medicinal products, as well as the identification of all suppliers of, or those supplied with, such active substances.

(15) The quality system should fully describe all key operations in appropriate documentation.

(16) Complaints, returns, and recalls should be recorded and handled carefully in accordance with established procedures. Records should be made available to the competent authorities. An assessment of returned active substances used as starting materials in veterinary medicinal products should be performed before any approval for resale.

(17) Any activity covered by good distribution practice for active substances used as starting materials in veterinary medicinal products that is outsourced should be correctly defined and agreed in order to avoid misunderstandings that could affect the integrity of such substances. A written contract between the contract giver and the contract acceptor should clearly establish the duties of each party.

(18) Regular self-inspections are necessary to monitor the implementation of and compliance with good distribution practice for active substances used as starting materials for veterinary medicinal products.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down the measures on good distribution practice for active substances used as starting materials in veterinary medicinal products.

2. This Regulation shall apply to importers and distributors of active substances used as starting materials in veterinary medicinal products, and to manufacturers who distribute active substances, which they manufactured, used as starting materials in veterinary medicinal products.

3. This Regulation shall not apply to intermediates of active substances used in veterinary medicinal products.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'good distribution practice for active substances used as starting materials in veterinary medicinal products' means the part of the quality assurance throughout the supply chain which ensures that the quality of active substances used as starting materials in veterinary medicinal products is maintained throughout all stages of the supply chain from the site of their manufacturer to the manufacturers of veterinary medicinal products;

(b) 'quality system' means the sum of all aspects of a system that implements quality policy and ensures that quality objectives are met;

(c) 'quality risk management' means a systematic process, applied both proactively and retrospectively, for the assessment, control, communication and review of risks to the quality of an active substance used as a starting material in veterinary medicinal products across the substance's lifecycle;

(d) 'procuring' means obtaining, acquiring or purchasing active substances used as starting materials in veterinary medicinal products from manufacturers, importers or other distributors;

(e) 'holding' means storing active substances used as starting materials in veterinary medicinal products;

(f) 'supplying' means all activities of providing, selling or donating active substances used as starting materials in veterinary medicinal products to distributors, pharmacists, manufacturers of veterinary medicinal products, or other persons in accordance with national law;

(g) 'deviation' means departure from approved documentation or an established standard;

(h) 'procedure' means a documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the distribution of active substances used as starting materials in veterinary medicinal products;

(i) 'distribution of active substances used as starting materials in veterinary medicinal products' means all activities consisting of procuring, importing, holding, supplying or exporting of active substances used as starting materials in veterinary medicinal products;

(j) 'documentation' means written procedures, instructions, contracts, records and data, in paper or in electronic form;

(k) 'signed' means the record of the individual who performed a particular action or review. This record can be initials, a full handwritten signature, a personal seal, or an advanced electronic signature as defined in Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council ([6]);

(l) 'expiry date' means the date placed on the container or labels of an active substance used as a starting material in veterinary medicinal products designating the time during which that active substance is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used;

(m) 'batch' means a defined quantity of starting material, packaging material or product processed in a single process or series of processes, so that it is expected to be homogeneous;

(n) 'retest date' means the date when an active substance used as a starting material in veterinary medicinal products should be re-examined to ensure that it is still suitable for use;

(o) 'transport' means moving active substances used as starting materials in veterinary medicinal products between two locations without storing them for unjustified periods of time;

(p) 'batch number' means a distinctive combination of numbers or letters that uniquely identifies a batch;

(q) 'contamination' means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or active substance during production, sampling, packaging or repackaging, storage or transport;

(r) 'calibration' means the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard;

(s) 'quarantined' means the status of materials isolated physically or by other effective means pending a decision on approval or rejection;

(t) 'qualification' means the action of proving that any equipment works correctly and actually leads to the expected results;

([6]) Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

(u) 'validation' means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria;

(v) 'falsified active substance used as a starting material in veterinary medicinal products' means any active substance used as a starting material in veterinary medicinal products with a false representation of any of the following:

(i) its identity, including its packaging and labelling, its name or its components as regards any of the ingredients and the strength of those ingredients;

(ii) its source, including its manufacturer, its country of manufacturing, its country of origin; or

(iii) its history, including the records and documents relating to the distribution channels used.

CHAPTER II

QUALITY SYSTEM

Article 3

Development and maintenance of a quality system

1. The persons referred to in Article 1(2) shall develop and maintain a quality system.

2. The quality system shall take into account the size, structure and complexity of the activities of those persons and the changes foreseen for those activities.

3. The persons referred to in Article 1(2) shall ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

Article 4

Requirements for the quality system

1. The quality system shall set out responsibilities, processes and quality risk management principles.

2. It shall ensure that the following obligations are fulfilled:

(a) the procuring, import, holding, supplying, transport or export of active substances used as starting materials in veterinary medicinal products comply with the requirements of good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation;

(b) management responsibilities are clearly specified;

(c) active substances used as starting materials in veterinary medicinal products are delivered under the right conditions, to the correct consignees and within an appropriate time period;

(d) records are made contemporaneously;

(e) deviations are documented and investigated;

(f) appropriate corrective and preventive actions ('CAPA') are taken in line with the principles of quality risk management;

(g) changes that may affect the storage and distribution of active substances used as starting materials in veterinary medicinal products are evaluated.

CHAPTER III

PERSONNEL

Article 5

Persons responsible for the quality system

1. The persons referred to in Article 1(2) shall designate a natural person as a person to be responsible for the quality system at each location where distribution activities are performed.

2. The persons responsible for the quality system shall have defined authority and responsibility for ensuring that a quality system is implemented and maintained as well as be personally responsible for fulfilling their obligations.

3. The persons responsible for the quality system may delegate their tasks but not their responsibilities.

Article 6

Personnel involved in the distribution of active substances used as starting materials in veterinary medicinal products

1. The responsibilities of all personnel involved in the distribution of active substances used as starting materials in veterinary medicinal products shall be specified in writing.

2. Personnel shall be trained on the requirements of good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation. Furthermore, personnel shall have the appropriate competence and experience to ensure that active substances used as starting materials in veterinary medicinal products are properly handled, stored and distributed.

Article 7

Training of personnel

1. Personnel shall receive initial and continuing training relevant to their role, based on procedures and in accordance with a written training programme.

2. The persons referred to in Article 1(2) shall keep a record of all training and periodically assess and document its effectiveness.

Article 8

Hygiene

The persons referred to in Article 1(2) shall establish appropriate procedures relating to personnel hygiene, including personal health and appropriate clothing, relevant to the activities carried out. Personnel shall comply with those procedures.

CHAPTER IV

PREMISES AND EQUIPMENT

Article 9

Requirements for premises and equipment

1. Premises and equipment shall be suitably located, designed, constructed and maintained to ensure:

(a) appropriate operations, such as receiving, proper storage, picking, packing and dispatch;

(b) protection from contamination, amongst other through narcotics, highly sensitising materials, materials of high pharmacological activity or toxicity;

(c) proper distribution of active substances used as starting materials in veterinary medicinal products.

2. There shall be sufficient space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness.

3. Monitoring devices that are necessary to guarantee the quality attributes of the active substances used as starting materials in veterinary medicinal products shall be subject to calibration against certified traceable standards, according to an approved schedule.

4. Receiving and dispatch activities shall, if possible, be done in separate places. If that is not possible, those activities shall be conducted at separate times.

5. Areas for receiving active substances used as starting materials in veterinary medicinal products shall protect deliveries from prevailing weather conditions during unloading.

6. The reception area shall be separate from the storage area.

7. Appropriate cleaning equipment and cleaning agents shall be chosen and used so as not to constitute a source of contamination.

8. Premises shall be protected from the entry of birds, rodents, insects and other animals. A rodent and a pest control programme shall be implemented and maintained. Its effectiveness shall be monitored.

9. Defective equipment shall not be used and shall either be removed or labelled as defective. Equipment shall be disposed of in such a way as to prevent any misuse.

10. Segregated areas shall be provided for the storage of received, quarantined, rejected, recalled and returned active substances used as starting materials in veterinary medicinal products, including those with damaged packaging.

11. Any system replacing physical segregation, as applicable, such as electronic segregation based on a computerised system, shall provide equivalent security and shall be subject to appropriate validation.

12. Segregated areas and products shall be appropriately identified.

Article 10

Access to premises

Access shall be controlled and premises shall be suitably secured to prevent unauthorised access.

CHAPTER V

DOCUMENTATION, PROCEDURES AND RECORD KEEPING

Article 11

Documentation

1. Documentation shall meet the following requirements:

(a) be readily available or retrievable;

(b) be sufficiently comprehensive with respect to the scope of the activities of the persons referred to in Article 1(2);

(c) be written in a language understood by personnel;

(d) be written in clear, unambiguous language.

2. When errors in the documentation are identified, they shall be corrected without delay, with clear traceability of who corrected them and when.

3. Any alteration made in the documentation shall be signed and dated. The alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.

4. Each employee shall have ready access to all necessary documentation for the tasks executed.

5. All documentation related to compliance of the persons referred to in Article 1(2) with good distribution practice for active substances used as starting materials in veterinary medicinal products as laid down in this Regulation shall be made available on request of competent authorities.

6. Relationships and control measures for original documents and official copies, data handling and records shall be stated for all paper-based, electronic and hybrid systems.

Article 12

Procedures

1. Procedures shall describe the distribution activities affecting the quality of the active substances used as starting materials in veterinary medicinal products. Those activities include:

(a) receipt and checking of deliveries;

(b) storage;

(c) cleaning and maintenance of the premises, including pest control;

(d) recording of the storage conditions;

(e) security of stocks on site and of consignments in transit;

(f) withdrawal from saleable stock;

(g) handling of returned active substances used as starting materials in veterinary medicinal products;

(h) recall plans.

2. Procedures shall be approved, signed and dated by the relevant person responsible for the quality system.

3. Valid and approved procedures shall be used. Documents shall be clear and appropriately detailed. The title, nature and purpose of documents shall be stated. Documents shall be reviewed regularly and kept up to date. Version control shall be applied to procedures. After revision of a document, a system shall exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures shall be removed from workstations and archived.

Article 13

Records

1. Records shall be clear, made at the time each operation is performed and in such a way that all significant activities or events are traceable.

2. Records shall be retained for at least 1 year after the expiry date of the active substance batch to which they relate. For active substances with retest dates, records shall be retained for at least 3 years after the batch is completely distributed.

3. Records shall ensure the traceability of the origin and destination of active substances used as starting materials in veterinary medicinal products, in order to identify all the suppliers of, or those supplied with those active substances. Records shall be kept of each purchase and sale. Records that shall be retained and be available include:

(a) the date of the transaction;

(b) name or designation of the active substances used as starting materials in veterinary medicinal products;

(c) original active substance manufacturer's batch number;

(d) quantity received or supplied;

(e) retest date or expiry date;

(f) name or company name and permanent address or registered place of business of the supplier and of the original active substance manufacturer, if not the same, or of the shipping agent or the consignee;

(g) purchase orders;

(h) bills of lading, transport and distribution records;

(i) receipt documents;

(j) certificates of analysis, including those of the original active substance manufacturer;

(k) any additional requirements specified by national law.

CHAPTER VI

OPERATIONS

Article 14

Verification of eligibility and approval of suppliers

Where active substances used as starting materials in veterinary medicinal products are procured from a manufacturer, importer or distributor established in the Union, the persons referred to in Article 1(2) shall verify that the respective manufacturer, importer or distributor is registered in accordance with Article 95(1) of Regulation (EU) 2019/6.

Article 15

Receipt of active substances used as starting materials

1. Deliveries shall be examined at receipt in order to check that:

(a) containers are not damaged;

(b) all relevant security seals are present with no sign of tampering;

(c) labelling is correct, including the correlation between the name used by the supplier and the in-house name, where different;

(d) necessary information, such as a certificate of analysis, is available;

(e) the active substances used as starting materials in veterinary medicinal products and the consignment correspond to the order.

2. Active substances used as starting materials in veterinary medicinal products with broken seals, damaged packaging, or suspected of possible contamination, shall be segregated physically or, if an equivalent electronic system is available, electronically and the cause of the issue investigated.

3. Active substances used as starting materials in veterinary medicinal products subject to special storage measures, such as narcotics and products requiring a specific storage temperature or humidity, shall immediately be identified and stored in accordance with written instructions and with relevant national law.

4. Where persons referred to in Article 1(2) suspect that an active substance used as a starting material in veterinary medicinal products procured or imported by them is a falsified active substance used as a starting material in veterinary medicinal products, they shall segregate it physically or, if an equivalent electronic system is available, electronically and inform the national competent authority of the Member State in which they are registered.

5. Rejected active substances used as starting materials in veterinary medicinal products shall be identified, controlled, segregated physically or, if an equivalent electronic system is available, electronically to prevent their unauthorised use in manufacturing and their further distribution. Records of destruction activities shall be readily available.

Article 16

Storage

1. Active substances used as starting materials in veterinary medicinal products shall be stored under the conditions specified by their manufacturer, such as controlled temperature and humidity when necessary, and in such a manner as to prevent contamination or mix-up. The storage conditions shall be monitored and records maintained. The records shall be reviewed regularly by the person responsible for the quality system.

2. When special storage conditions are required, the storage area shall be subject to qualification and operated within the specified limits.

3. The storage facilities shall be clean and free from litter, dust and pests and other animals. Adequate precautions shall be taken against spillage or breakage and contamination.

4. There shall be a system to ensure stock rotation, such as 'first expiry or retest date, first out', with regular and frequent checks that the system is operating correctly. Electronic warehouse management systems shall be subject to validation.

5. Active substances used as starting materials in veterinary medicinal products beyond their expiry date shall be segregated physically or, if an electronic system is available, electronically from approved stock and not be supplied.

Article 17

Outsourced activities

1. Where storage or transport of active substances used as starting materials in veterinary medicinal products is contracted out, the persons referred to in Article 1(2) shall ensure that the contract acceptor knows and follows the appropriate storage and transport conditions.

2. There shall be a written contract between the contract giver and contract acceptor, which clearly establishes the duties of each party.

3. The contract acceptor shall not subcontract any of the work under the contract to a third party without the contract giver's written authorisation.

Article 18

Deliveries to customers

1. In the case of supplies within the Union, the persons referred to in Article 1(2) shall only supply active substances used as starting materials in veterinary medicinal products to other distributors, manufacturers, dispensing pharmacies or to persons permitted by national law.

2. Active substances used as starting materials in veterinary medicinal products shall be transported in accordance with the conditions specified by their manufacturer and in a manner that does not adversely affect their quality. Product, batch and container identity shall be maintained at all times. All original container labels shall remain readable. Actions shall be taken to prevent unauthorised access to the active substances used as starting materials in veterinary medicinal products being transported.

3. A system shall be in place by which the distribution of each batch of active substance used as a starting material in veterinary medicinal products can be readily identified to permit its recall.

Article 19

Transfer of information

1. The persons referred to in Article 1(2) shall notify relevant customers of any information or event that they become aware of which has potential to cause an interruption to supply.

2. The persons referred to in Article 1(2) shall transfer all quality or regulatory information about the active substances used as starting materials in veterinary medicinal products received from the original manufacturer of those active substances to the relevant customer and all such information received from the customer to the original manufacturer of those active substances.

3. The persons referred to in Article 1(2) shall provide to the relevant customer the name or company name and permanent address or registered place of business of the original active substance manufacturer and the batch numbers supplied. A copy of the original certificate of analysis from the original active substance manufacturer shall be provided to the customer.

4. The persons referred to in Article 1(2) shall provide the name or company name and permanent address or registered place of business of the original active substance manufacturer to competent authorities upon request. The original active substance manufacturer may respond to the competent authority either directly or through agents it has authorised.

CHAPTER VII

COMPLAINTS, RETURNS AND RECALLS

Article 20

Complaints

1. Complaints, whether received orally or in writing, shall be recorded and investigated according to a procedure.

In the event of a complaint about the quality of an active substance used as a starting material in veterinary medicinal products, the persons referred to in Article 1(2) shall review the complaint with the original active substance manufacturer, as applicable, in order to determine whether any further action shall be initiated either with other customers who may have received that active substance, or with the competent authority, or both. The investigation into the cause for the complaint shall be conducted and documented by the appropriate party.

2. Complaint records shall include the following:

(a) name or company name and permanent address or registered place of business of complainant;

(b) name, title, where appropriate, and contact details of the person submitting the complaint;

(c) nature of the complaint, including name and batch number of the active substance used as a starting material in veterinary medicinal products which is the subject of that complaint;

(d) date the complaint is received;

(e) action initially taken, including dates and identity of the person taking that action;

(f) any follow-up action taken;

(g) response provided to the originator of the complaint, including the date of the response;

(h) final decision on the active substance batch concerned.

3. Records of complaints shall be retained in order to evaluate trends, product related frequencies, and severity, with a view to taking additional, and if appropriate, immediate corrective action. Those records shall be made available to the competent authorities during inspections.

4. Where a complaint is referred to the original active substance manufacturer, the record maintained by the person referred to in Article 1(2) shall include any response received from the original active substance manufacturer, including the date and information provided.

5. In the event of a serious or potentially life-threatening situation, the persons referred to in Article 1(2) shall inform, seek advice from and follow the instructions of local, national or international authorities, as appropriate.

Article 21

Returns

1. Returned active substances used as starting materials in veterinary medicinal products shall be identified as such and segregated physically or, if an equivalent electronic system is available, electronically, pending the outcome of an investigation into those returned active substances.

2. Active substances used as starting materials in veterinary medicinal products which have left the care of the persons referred to in Article 1(2) shall only be returned to saleable stock if all of the following conditions are met:

(a) the active substance used as a starting material in veterinary medicinal products is in its original unopened containers with all original security seals present and is in good condition;

(b) it is demonstrated by written information provided by the customer that the active substance used as a starting material in veterinary medicinal products has been stored and handled under proper conditions;

(c) the remaining shelf life is acceptable;

(d) the active substance used as a starting material in veterinary medicinal products has been examined and assessed by a person trained and authorised to do so;

(e) no loss of information or traceability has occurred.

3. The assessment under paragraph (2) shall take into account the nature of the active substance used as a starting material in veterinary medicinal products, any special storage conditions it requires and the time elapsed since it was supplied. As necessary and if there is any doubt about the quality of the returned active substance used as a starting material in veterinary medicinal products, advice shall be sought from the original active substance manufacturer.

4. Records of returned active substances used as starting materials in veterinary medicinal products shall be maintained. For each return, documentation shall include the following:

(a) name or company name and permanent address or registered place of business of the consignee returning the active substance used as starting materials in veterinary medicinal products;

(b) name or designation of the active substance used as a starting material in veterinary medicinal products;

(c) batch number of the active substance used as a starting material in veterinary medicinal products;

(d) quantity of active substance used as a starting material in veterinary medicinal products returned;

(e) reason for return;

(f) use or disposal of the returned active substance used as a starting material in veterinary medicinal products and records of the assessment performed.

5. Only appropriately trained and authorised personnel shall release active substances used as starting materials in veterinary medicinal products for return to saleable stock.

6. Active substances used as starting materials in veterinary medicinal products returned to saleable stock shall be placed so that the stock rotation system operates effectively.

Article 22

Recalls

1. There shall be a procedure in place that defines the circumstances under which a recall of an active substance used as a starting material in veterinary medicinal products shall be considered.

2. The recall procedure shall specify:

(a) who shall be involved in evaluating the information;

(b) how a recall shall be initiated;

(c) who shall be informed about the recall;

(d) how the recalled material shall be treated.

3. The person responsible for the quality system shall be involved in recalls.

CHAPTER VIII

SELF-INSPECTIONS AND FINAL PROVISIONS

Article 23

Self-inspections

1. The persons referred to in Article 1(2) shall conduct and record self-inspections in order to monitor the implementation of and compliance with good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation.

2. Regular self-inspections shall be performed in accordance with a schedule set out in the quality system.

3. Self-inspections shall be conducted in an impartial and detailed way by designated competent company personnel.

4. The results of all self-inspections shall be recorded. Reports shall contain all observations made during the inspection and be presented to the relevant personnel as well as management.

5. Necessary CAPA shall be taken and the effectiveness of the CAPA shall be reviewed.

Article 24

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN